# UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

IN RE: BIOPURE SECURITIES
LITIGATION

OUT OF THE PROPERTY OF T

# ANSWER, AFFIRMATIVE DEFENSES AND JURY DEMAND

Defendants Biopure Corporation ("Biopure"), Thomas A. Moore ("Moore"), Carl W. Rausch ("Rausch"), Ronald F. Richards ("Richards"), Howard P. Richman ("Richman"), Charles A. Sanders ("Sanders"), and J. Richard Crout ("Crout") (hereinafter collectively "Defendants") by their attorneys, Bingham McCutchen LLP, hereby answer the Amended Complaint dated March 28, 2006 by numbered Paragraphs corresponding to those of the Amended Complaint as follows:

# **ANSWER**

Defendants aver that the un-numbered Paragraph preceding Paragraph 1 of the Complaint contains no factual allegations, but rather describes the Complaint and matters purportedly pertaining to Plaintiffs' counsel, and no answer is required. To the extent an answer is required, Defendants deny the allegations in the un-numbered Paragraph preceding Paragraph 1 of the Complaint.

### **INTRODUCTION**

- 1. Defendants deny the allegations of Paragraph 1, except Defendants admit that the named defendants are all past or present officers or directors of Biopure.
- 2. Defendants deny the allegations of Paragraph 2, except Defendants admit that Biopure develops, manufactures and markets oxygen therapeutics for both human and veterinary use. Defendants further admit that Biopure has developed and manufactures two biologic products: Hemopure 250 (bovine), or HBOC-201, for human use ("Hemopure"), and Oxyglobin hemoglobin glutamer 200 (bovine), or HBOC-301, for veterinary use

("Oxyglobin"). Defendants further admit that Oxyglobin is approved for use in the United States for administration to dogs and that Hemopure is not approved for any human use in the United States; but Hemopure is approved in South Africa for use in severely anemic surgery patients.

- 3. Defendants deny the allegations of Paragraph 3, except Defendant Biopure admits it submitted a biologics license application to the Food and Drug Administration ("FDA") in or about July 2002 seeking approval to use Hemopure in the treatment of orthopedic surgery patients (the "BLA").
  - 4. Defendants deny the allegations of Paragraph 4.
- 5. Defendants deny the allegations of Paragraph 5, except Defendant Biopure admits that on or about April 9, 2003, the FDA placed a clinical hold on one single proposed protocol entitled "A Multi-Center Study to Evaluate the Safety and Tolerability of Hemoglobin-Based Oxygen Carrier 201 (HBOC-201) in Trauma Subjects" (the "In-Hospital Trauma Protocol").
- 6. Defendants deny the allegations of Paragraph 6, except Defendant Biopure admits the that the FDA declined to lift the clinical hold on the In-Hospital Trauma Protocol in or about May 2003.
- 7. Defendants deny the allegations of Paragraph 7, except Defendant Biopure admits that FDA sent two letters to Biopure dated July 30, 2003 separately communicating about the BLA and the In-Hospital Trauma Protocol and refers to the letters themselves for the complete contents thereof. Further answering, Defendant Biopure states that the July 30 letter regarding the BLA did not refer to itself as a complete response letter and the FDA's conduct after the letter confirmed it was not a complete response letter.
- 8. Defendants deny the allegations of Paragraph 8, except Defendant Biopure admits that FDA sent two letters to Biopure dated July 30, 2003 separately communicating about the BLA and the In-Hospital Trauma Protocol and refers to the letters themselves for the complete contents thereof. Further answering, Defendant Biopure states that the July 30 letter regarding the BLA did not refer to itself as a complete response letter and the FDA's conduct after the letter confirmed it was not a complete response letter.

- 9. Defendants deny the allegations of Paragraph 9.
- 10. Defendants deny the allegations of Paragraph 10.
- 11. Defendants deny the allegations of Paragraph 11, and refer to historical price information regarding its stock price.
- 12. Defendants deny the allegations of Paragraph 12, except Defendant Biopure admits that it issued a press release on December 24 and refers to the December 24 Press Release and the December 24 Form 8-K for the complete terms and contents thereof.
  - 13. Defendants deny the allegations of Paragraph 13.

# **JURISDICTION AND VENUE**

- 14. Paragraph 14 sets forth the statutory basis for this action to which no response is required.
- 15. Paragraph 15 sets forth the statutory basis for this action to which no response is required.
- 16. Defendants deny the allegations of Paragraph 16, except Defendant Biopure admits that its principal place of business is located in Cambridge, Massachusetts.
- 17. Defendants deny the allegations of Paragraph 17, except that Defendant Biopure admits that from time to time it has used the mails or the means or instruments of transportation or communication in interstate commerce. Further answering, Defendants deny liability under any of the theories set forth in this Complaint.

# **PARTIES**

- 18. Defendants are without knowledge or information sufficient to form a belief as to the truth of the statements of Paragraph 18.
- 19. Defendants are without knowledge or information sufficient to form a belief as to the truth of the statements of Paragraph 19.
- 20. Defendants are without knowledge or information sufficient to form a belief as to the truth of the statements of Paragraph 20.

- 21. Defendants are without knowledge or information sufficient to form a belief as to the truth of the statements of Paragraph 21.
- 22. Defendants admit that Biopure is a Delaware corporation, with its principal place of business in Cambridge, Massachusetts.
- 23. Defendant Moore admits that he was Biopure's President and Chief Executive Officer and a director of Biopure during April 9, 2003 through December 24, 2003.
- 24. Defendant Rausch admits that he was Biopure's Vice Chairman and Chief Technical Officer and a director of Biopure during April 9, 2003 through December 24, 2003.
- 25. Defendant Richards admits that he was Biopure's Chief Financial Officer and Senior Vice President Business Development during April 9, 2003 through December 24, 2003.
- 26. Defendant Richman admits that he was Biopure's Senior Vice-President of Regulatory Affairs and Operations during April 9, 2003 until October 2003
- 27. Defendant Sanders admits that he was a director and Chairman of the Board of Directors of Biopure during April 9, 2003 through December 24, 2003.
- 28. Defendant Crout denies the allegations of Paragraph 28 except admits that he was a director of Biopure during April 9, 2003 through December 24, 2003.
- 29. Paragraph 29 sets forth the manner in which the Defendants will be referred, to which no response is required.
- 30. Paragraph 30 sets forth the manner in which the Defendants will be referred, to which no response is required.

# **BACKGROUND**

- 31. Defendants deny the allegations of Paragraph 31 and refer to the United States Code and the Code of Federal Regulations regarding the FDA.
- 32. Defendants deny the allegations of Paragraph 32 and refer to the United States Code and the Code of Federal Regulations regarding the FDA.
- 33. Defendants deny the allegations of Paragraph 33 and refer to the United States Code and the Code of Federal Regulations regarding the FDA.

- 34. Defendants deny the allegations of Paragraph 34 and refer to the United States Code and the Code of Federal Regulations regarding the FDA.
- 35. Defendants deny the allegations of Paragraph 35 and refer to United States Code and the Code of Federal Regulations regarding the FDA.
- 36. Defendants deny the allegations of Paragraph 36, except Defendant Biopure admits it manufactures two products: Hemopure and Oxyglobin.
- 37. Defendants deny the allegations of Paragraph 37, except Defendant Biopure admits that Hemopure has been approved for marketing for an indication in South Africa and that the FDA has not approved Hemopure for marketing for an indication in the United States.
- 38. Defendants deny the allegations of Paragraph 38, except Defendant Biopure admits that it was founded in 1984 and that information about its finances is set forth in its periodic filings and refers to those periodic filings for the complete contents thereof
- 39. Defendants deny the allegations of Paragraph 39, except Defendant Biopure admits that it made a filing of the type listed on the date listed and refers to that filing for the complete contents thereof.

# **Background Information Regarding the Hemopure BLA**

- 40. Defendants deny the allegations of Paragraph 40, except Defendant Biopure admits that it submitted the BLA on or about July 31, 2002.
- 41. Defendants deny the allegations of Paragraph 41, except Defendant Biopure admits that it submitted the BLA on or about July 31, 2002 and refers to the BLA for the complete contents thereof.
- 42. Defendants deny the allegations of Paragraph 42, except Defendant Biopure admits that it issued a letter to shareholders that was contained in Biopure's 2002 Annual Report to shareholders dated February 4, 2003, partially quoted in Paragraph 42, and refers to the 2002 Annual Report to Shareholders which contains the Company's 2002 Form 10-K for the complete contents thereof.

- 43. Defendants deny the allegation of Paragraph 43, except Defendant Biopure admits it received grants from the United States Department of the Army. Further answering, Defendant Biopure admits that the selected excerpt is an accurate quote from the 2002 Annual Report to Shareholders and refers to the 2002 Annual Report to Shareholders which contains the Company's 2002 Form 10-K for the complete contents thereof.
  - 44. Defendants deny the allegations of Paragraph 44

# SUBSTANTIVE ALLEGATIONS

- 45. Defendants deny the allegations of Paragraph 45. Further answering, Defendant Biopure admits on or about March 7, 2003, Biopure submitted the In-Hospital Trauma Protocol and that the FDA assigned the In-Hospital Trauma Protocol to a separate Investigational New Drug Application ("IND") from the IND for the pending BLA.
- 46. Defendants deny the allegations of Paragraph 46, except Defendant Biopure admits that on or about April 9, 2003, FDA placed the In-Hospital Trauma Trial on clinical hold.
- 47. Defendants deny the allegations of Paragraph 47, except Defendant Biopure admits that on or about April 9, 2003, FDA placed the In-Hospital Trauma Trial on clinical hold.
- 48. Defendants deny the allegations of Paragraph 48, except Defendant Moore admits that he did not participate in a telephone call with the FDA on April 9, 2003.
  - 49. Defendants deny the allegations of Paragraph 49.
  - 50. Defendants deny the allegations of Paragraph 50.
- 51. Defendants deny the allegations of Paragraph 51, except Defendant Biopure admits that it made public statements from time to time during April 9, 2003 through December 24, 2003 and refers to those public statements for the complete contents thereof.
  - 52. Defendants deny the allegations of Paragraph 52.
- 53. Defendants deny the allegations of Paragraph 53. Further answering, Defendant Biopure admits that it made a filing of the type listed on the date listed and refers to the filing for the complete contents thereof.
  - 54. Defendants deny the allegations of Paragraph 54.

- 55. Defendants deny the allegations of Paragraph 55.
- 56. Defendants deny the allegations of Paragraph 56, except Defendant Biopure admits that it filed registration statements with the SEC during April 9, 2003 through December 24, 2003 and refers to those registration statements for the complete contents thereof.
- 57. Defendants deny the allegations of Paragraph 57, except Defendant Biopure admits that it made a filing of the type listed on the date listed and refers to the filing for the complete contents thereof.
- 58. Defendants deny the allegations of Paragraph 58, except Defendant Biopure admits that it made a filing of the type listed on the date listed and refers to the filing for the complete contents thereof.
- 59. Defendants deny the allegations of Paragraph 59, except Defendant Biopure admits that it made filings of the types listed on the dates listed and refers to the filings for the complete contents thereof.
- 60. Defendants deny the allegations of Paragraph 60, except Defendant Biopure admits that it made a filing of the type listed on the date listed and refers to that filing for the complete contents thereof.
  - 61. Defendants deny the allegations of Paragraph 61.
- 62. Defendants deny the allegations of Paragraph 62, except Defendant Biopure admits issuing a press release on April 24, 2003 and refers to the April 24, 2003 press release for the complete contents thereof.
  - 63. Defendants deny the allegations of Paragraph 63.
- 64. Defendants deny the allegations of Paragraph 64, except Defendant Biopure admits it received a letter from the FDA stamped April 25, 2003, and refers to the letter for the complete contents thereof.
- 65. Defendants deny the allegations of Paragraph 65, except Defendant Biopure admits that it made filings of the types listed on the dates listed and refers to those filings for the complete contents thereof. Richman denies the allegations contained in Paragraph 65 that refer

specifically to him. Richman is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations contained in Paragraph 65.

- 66. Defendants deny the allegations of Paragraph 66.
- 67. Defendants deny the allegations of Paragraph 67, except Defendant Biopure admits that it made a submission to the FDA dated May 12, 2003 and Biopure refers to the submission for the complete contents thereof. Richman admits that on May 12, 2003, he participated in the drafting of and signed a letter to the FDA, which responded to the FDA's April 25, 2003 letter. Richman is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations contained in Paragraph 67.
- 68. Defendants deny the allegations of Paragraph 68, except Defendant Biopure admits that it made a filing of the type listed on the date listed and refers to that filing for the complete contents thereof.
  - 69. Defendants deny the allegations of Paragraph 69.
- 70. Defendants deny the allegations of Paragraph 70, except Defendant Biopure admits that it issued a press release dated May 22, 2003 and made a filing of the type listed and refers to that press release and that filing for the complete contents thereof. Richman denies the allegations in Paragraph 70 that refer specifically to him. Richman is without sufficient knowledge or information to form a belief as to the remaining allegations contained in Paragraph 70 pertaining to the other Defendants.
- 71. Defendants deny the allegations of Paragraph 71, except that Defendant Biopure admits that it issued a press release dated May 22, 2003 and refers to that press release for the complete contents thereof.
- 72. Defendants deny the allegations of Paragraph 72, except Defendants Biopure, Moore, Richards and Richman admit that they participated in a conference call on or about May 22, 2003 and refer to the entire transcript of the call for a rendition of the contents thereof.
- 73. Defendants deny the allegations of Paragraph 73, except Defendants refer to the transcript of the May 22, 2003 call for a rendition of the contents thereof. Answering further,

Defendant Moore specifically denies that he made any false, misleading, or deceptive statements during the May 22, 2003 call.

- 74. Defendants deny the allegations of Paragraph 74. Answering further, Defendant Moore specifically denies that he misrepresented any information that Biopure had received from FDA.
  - 75. Defendants deny the allegations in Paragraph 75.
- 76. Defendants deny the allegations of Paragraph 76, except Defendant Biopure admits it issued a press release dated May 22, 2003 and refers to that press release for the complete contents thereof.
- 77. Defendants deny the allegations of Paragraph 77, except Defendant Biopure admits that it received two letters from the FDA stamped May 30, 2003 and refers to those letters for the complete contents thereof. Richman admits that the two letters referenced in Paragraph 77 were addressed to him; otherwise, denied.
- 78. Defendants deny the allegations of Paragraph 78. Richman admits that he received the two letters referenced in Paragraph 78 were addressed to him; otherwise, denied.
- 79. Defendants deny the allegations of Paragraph 79, except Defendant Biopure admits that it issued a press release dated May 30, 2003 and refers to that press release for the complete contents thereof. Richman denies the allegations in Paragraph 79 that refer specifically to him. Richman is without sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 79 that refer to other Defendants.
- 80. Defendants deny the allegations of Paragraph 80, except Defendant Biopure admits that it issued a press release dated May 30, 2003 and refers to that press release for the complete contents thereof.
  - 81. Defendants deny the allegations of Paragraph 81.
- 82. Defendants deny the allegations of Paragraph 82, except Defendant Biopure admits it issued a press release dated May 30, 2003 and refers to that press release for the complete contents thereof.

- 83. Defendants deny the allegations of Paragraph 83, except that Defendants Moore, Richman and Richards admit that they participated in a conference call on or about May 30, 2003 and refer to the transcript of the May 30, 2003 call for a rendition of the contents thereof. Answering further, Defendant Moore specifically denies that he made any false, deceptive, or misleading statements or had any intent to falsely characterize any action taken by FDA, during the May 30, 2003 call.
- 84. Defendants deny the allegations of Paragraph 84, except that Defendants Moore, Richman and Richards admit that they participated in a conference call on or about May 30, 2003 and refer to the transcript of the May 30, 2003 call for a rendition of the contents thereof.
  - 85. Defendants deny the allegations of Paragraph 85.
- 86. Defendants deny the allegations of Paragraph 86, except Defendant Biopure admits that it made a filing of the type listed on the date listed and refers to the filing for the complete contents thereof. Richman denies the allegations in Paragraph 86 that refer specifically to him. Richman is without sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 86 pertaining to other Defendants.
- 87. Defendants deny the allegations of Paragraph 87, except Defendant Biopure admits that it made a filing of the type listed on the date listed and refers to the filing for the complete contents thereof.
- 88. Defendants deny the allegations of Paragraph 88, except Defendant Biopure admits that it made a filing of the type listed on the date listed and refers to the filing for the complete contents thereof.
- 89. Defendants deny the allegations of Paragraph 89, except Defendant Biopure admits that it made a filing of the type listed on the date listed and refers to the filing for the complete contents thereof.
- 90. Defendants deny the allegations of Paragraph 90, except Defendant Biopure admits that it made filings of the type listed on the dates listed and refers to the filings for the complete contents thereof.

- 91. Defendants deny the allegations of Paragraph 91.
- 92. Defendants deny the allegations in Paragraph 92, except Defendant Biopure admits that it made a submission to FDA dated July 2, 2003 and refers to the submission for the complete contents thereof. Richman admits that on or about July 2, 2003 Biopure submitted a letter to the FDA. Further answering, Richman admits the first clause of the second sentence in Paragraph 92 and Richman is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations contained in the second sentence of Paragraph 92.
- 93. Defendants deny the allegations of Paragraph 93, except Defendant Biopure admits it made a filing of the type listed on the date listed and refers to the filing for the complete contents thereof.
  - 94. Defendants deny the allegations of Paragraph 94.
- 95. Defendants deny the allegations of Paragraph 95, except Defendant Biopure admits that it made a filing of the type listed on the date listed and refers to that filing for the complete contents thereof. Richman denies the allegations in Paragraph 95 that refer specifically to him. Richman is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations contained in Paragraph 95.
  - 96. Defendants deny the allegations of Paragraph 96.
- 97. Defendants deny the allegations of Paragraph 97, except that Defendant Biopure admits it issued a press release dated July 23, 2003 and refers to that press release for the complete contents thereof.
- 98. Defendants deny the allegations of Paragraph 98, except Defendant Biopure admits it received two letters from FDA stamped July 30, 2003 and refers to those two letters for the complete contents thereof. Further answering, Defendant Biopure states that the July 30 letter regarding the BLA did not refer to itself as a complete response letter and the FDA's conduct after the letter confirmed it was not a complete response letter. Richman admits that he received the letters referred to in Paragraph 98; otherwise denied.

- 99. Defendants deny the allegations of Paragraph 99. Further answering, Defendant Biopure states that the July 30 letter regarding the BLA did not refer to itself as a complete response letter and the FDA's conduct after the letter confirmed it was not a complete response letter.
- 100. Defendants deny the allegations of Paragraph 100, except that Defendant Biopure admits that it received two letters from FDA stamped July 30, 2003, and refers to those two letters for the complete contents thereof. Further answering, Defendant Biopure states that the July 30 letter regarding the BLA did not refer to itself as a complete response letter and the FDA's conduct after the letter confirmed it was not a complete response letter.
- 101. Defendants deny the allegations of Paragraph 101, except Defendant Biopure admits that it received two letters from FDA stamped July 30, 2003 and refers to the those two letters for the complete contents thereof. Further answering, Defendant Biopure states that the July 30 letter regarding the BLA did not refer to itself as a complete response letter and the FDA's conduct after the letter confirmed it was not a complete response letter.
- 102. Defendants deny the allegations of Paragraph 102, except Defendant Biopure admits that it received two letters from FDA stamped July 30, 2003 and refers to those two letters for the complete contents thereof. Further answering, Defendant Biopure states that the July 30 letter regarding the BLA did not refer to itself as a complete response letter and the FDA's conduct after the letter confirmed it was not a complete response letter.
- 103. Defendants deny the allegations of Paragraph 103, except Defendant Biopure admits that it received two letters from FDA stamped July 30, 2003 and refers to the those two letters for the complete contents thereof. Further answering, Defendant Biopure states that the July 30 letter regarding the BLA did not refer to itself as a complete response letter and the FDA's conduct after the letter confirmed it was not a complete response letter.
- 104. Defendants deny the allegations of Paragraph 104, except Defendant Biopure admits that it received two letters from FDA stamped July 30, 2003 and refers to the those two letters for the complete contents thereof. Further answering, Defendant Biopure states that the

July 30 letter regarding the BLA did not refer to itself as a complete response letter and the FDA's conduct after the letter confirmed it was not a complete response letter.

- 105. Defendants deny the allegations of Paragraph 105. Further answering, Defendant Biopure states that the July 30 letter regarding the BLA did not refer to itself as a complete response letter and the FDA's conduct after the letter confirmed it was not a complete response letter.
- 106. Defendant Biopure denies the allegations of Paragraph 106. Richman denies the allegations contained in Paragraph 106.
- 107. Defendants deny the allegations of Paragraph 107, except Defendant Biopure admits that on or about July 31, 2003 it communicated with outside counsel. Answering further, Defendant Moore specifically denies that Biopure's General Counsel informed him of the substance of any comments by outside counsel on or about July 31, 2003. Richman denies the allegations contained in Paragraph 107 that refer specifically to him. Richman is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 107.
- 108. Defendants deny the allegations of Paragraph 108, except Defendant Biopure admits it issued a press release dated August 1, 2003 and refers to that press release for the complete contents thereof. Richman admits that he participated in reviewing the August 1 Press Release and denies the remaining allegations that refer specifically to him.
- 109. Defendants deny the allegations of Paragraph 109, except Defendant Biopure admits it issued a press release dated August 1, 2003 and refers to that press release for the complete contents thereof.
  - 110. Defendants deny the allegations of Paragraph 110.
- 111. Defendants deny the allegations of Paragraph 111, except Defendant Biopure admits that it made a filing of the type listed and refers to that filing for the complete contents thereof.

- 112. Defendants deny the allegations of Paragraph 112, except Defendant Biopure admits the August 1, 2003 Press Release was issued on the morning of August 1, 2003 and refers to that press release for the complete contents thereof and refers to the historical price information regarding its stock price.
- 113. Defendants deny the allegations in Paragraph 113, except Defendant Biopure admits that it communicated with outside counsel in August 2003. Further answering Defendant Biopure states that the July 30 letter regarding the BLA did not refer to itself as a complete response letter and the FDA's conduct after the letter confirmed it was not a complete response letter.
- 114. Defendants deny the allegations of Paragraph 114, except Defendant Biopure refers to historical price information regarding its stock price.
- 115. Defendants deny the allegations of Paragraph 115, except Defendant Biopure admits it issued a press release dated August 21, 2003 and refers to that press release for the complete contents thereof. Richman denies the allegations in Paragraph 115 that refer specifically to him. Richman is without sufficient knowledge or information to form a belief as to the truth of the allegations contained in Paragraph 115.
- 116. Defendants deny the allegations of Paragraph 116, except Defendant Biopure admits that it issued a press release dated August 21, 2003 and refers to that press release for the complete contents thereof.
  - 117. Defendants deny the allegations of Paragraph 117.
- 118. Defendants deny the allegations of Paragraph 118, except Defendant Biopure admits that it issued a press release dated August 21, 2003 and made a filing of the type listed and refers to that press release and that filing for the complete contents thereof.
- 119. Defendants deny the allegations of Paragraph 119, except Defendant Biopure refers to the entire transcripts of investor calls for a rendition of the contents thereof. Richman admits that he and Defendant Moore participated in a conference call on August 21, 2003.

- 120. Defendants deny the allegations of Paragraph 120, except Defendant Biopure refers to the entire transcripts of investor calls for a rendition of the contents thereof.
- 121. Defendants deny the allegations Paragraph 121, except Defendant Biopure refers to the entire transcript of investor calls for a rendition of the contents thereof.
- 122. Defendants deny the allegations of Paragraph 122. Answering further, Defendant Moore specifically denies that his alleged statements lacked a basis in fact or were inconsistent with any communications Biopure had received from FDA.
- 123. Defendants deny the allegations of Paragraph 123, except Defendant Biopure refers to historical price information regarding its stock price.
- 124. Defendants deny the allegations of Paragraph 124, except Defendant Biopure admits that it made filings of the type listed on the dates listed and refers to those filings for the complete contents thereof. Richman denies the allegations in Paragraph 124 that refer specifically to him. Richman is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 124 pertaining to the other Defendants.
- 125. Defendants deny the allegations of Paragraph 125, except Defendant Biopure admits that it made filings of the types listed on the dates listed and refers to those filings for the complete contents thereof. Further answering, Defendant Biopure states that the July 30 letter regarding the BLA did not refer to itself as a complete response letter and the FDA's conduct after the letter confirmed it was not a complete response letter.
  - 126. Defendants deny the allegations of Paragraph 126.
- 127. Defendants deny the allegations of Paragraph 127, except that Defendant Biopure admits that it communicated with outside counsel in August 2003. Richman denies the allegations in Paragraph 127 that refer specifically to him. Richman is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 127 pertaining to the other Defendants.
- 128. Defendants deny the allegations of Paragraph 128, except Defendant Biopure admits that it made a filing of the type listed on the date listed and refers to that filing for the

complete contents thereof. Further answering, Defendant Biopure states that the July 30 letter regarding the BLA did not refer to itself as a complete response letter and the FDA's conduct after the letter confirmed it was not a complete response letter.

- 129. Defendants deny the allegations of Paragraph 129, except Defendant Biopure admits that it made a filing of the type listed on the date listed and refers to that filing for the complete contents thereof. Richman denies the allegations in Paragraph 129 that refer specifically to him. Richman is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 129 pertaining to the other Defendants.
- 130. Defendants deny the allegations of Paragraph 130, except Defendant Biopure admits that it made a filing of the type listed on the date listed and refers to that filing for the complete contents thereof. Richman admits that he reviewed the document referenced at Paragraph 130 from a regulatory perspective. Richman denies all other allegations in Paragraph 130 that refer to him. Richman is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 130 pertaining to the other Defendants.
- 131. Defendants deny the allegations of Paragraph 131, except Defendant Biopure admits that it made filings of the type listed on the dates listed and refers to those filings for the complete contents thereof. Further answering, Defendant Biopure states that the July 30 letter regarding the BLA did not refer to itself as a complete response letter and the FDA's conduct after the letter confirmed it was not a complete response letter.
  - 132. Defendant Biopure denies the allegations of Paragraph 132.
- 133. Defendants deny the allegations of Paragraph 133, except Defendant Biopure admits it filed a press release dated September 10, 2003 and refers to that press release for the complete contents thereof.
- 134. Defendants deny the allegations of Paragraph 134, except Defendant Biopure admits that Defendant Moore gave a presentation on or about September 17, 2003. Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining statements of Paragraph 134.

- 135. Defendants deny the allegations of Paragraph 135.
- 136. Defendants deny the allegations of Paragraph 136. Answering further, Defendant Moore specifically denies that the referenced statement was false, deceptive, or misleading.
- 137. Defendants deny the allegations of Paragraph 137. Answering further, Defendant Moore specifically denies that the referenced presentation was false, deceptive, or misleading in whole or in part.
- 138. Defendants deny the allegations of Paragraph 138, except Defendant Biopure admits that it issued a press release dated September 18, 2003 and refers to that press release for complete contents thereof.
- 139. Defendants deny the allegations of Paragraph 139, except Defendant Biopure admits that Defendant Moore made a presentation on or about September 25, 2003. Further answering, Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining statements of Paragraph 139.
  - 140. Defendants deny the allegations of Paragraph 140.
- 141. Defendants deny the allegations of Paragraph 141. Answering further, Defendant Moore specifically denies that the referenced statement was false, deceptive, or misleading.
- 142. Defendants deny the allegations of Paragraph 142. Answering further, Defendant Moore specifically denies that the referenced presentation was false, deceptive, or misleading in whole or in part.
- 143. Defendants deny the allegations of Paragraph 143, except Defendant Biopure admits that it issued a press release dated October 30, 2003 and made a filing of the type listed and refers to that press release and that filing for the complete contents thereof.
  - 144. Defendants deny the allegations of Paragraph 144.
- 145. Defendants deny the allegations of Paragraph 145, except Defendant Biopure admits that it issued a press release dated October 30, 2003 and refers to the that press release for the complete contents thereof.

- 146. Defendants deny the allegations of Paragraph 146, except Defendant Biopure admits that it issued a press release dated October 30, 2003 and refers to that press release for the complete contents thereof.
- 147. Defendants deny the allegations of Paragraph 147. Answering further, Defendant Moore specifically denies that the referenced statement was false, deceptive, or misleading.
- 148. Defendants deny the allegations of Paragraph 148, except Defendant Biopure admits that it issued a press release dated October 30, 2003 and refers to that press release for the complete contents thereof.
- 149. Defendants deny the allegations of Paragraph 149, except Defendant Biopure refers to the entire transcript of investor calls for a rendition of the contents thereof.
- 150. Defendants deny the allegations of Paragraph 150, except Defendant Biopure refers to the entire transcript of investor calls for a rendition of the contents thereof.
- 151. Defendants deny the allegation of Paragraph 151. Answering further, Defendant Moore specifically denies that the referenced statements were false or misleading in whole or in part.
- 152. Defendants deny the allegations of Paragraph 152, except Defendant Biopure refers to historical price information regarding its stock price.
  - 153. Defendants deny the allegations of Paragraph 153.
- 154. Defendants deny the allegations of Paragraph 154, except Defendant Biopure refers to historical price information regarding its stock price.
- 155. Defendants deny the allegations of Paragraph 155, except that Defendant Biopure admits that it issued a press release dated October 30, 2003 and refers to that press release for the complete contents thereof.
- 156. Defendants deny the allegations of Paragraph 156, except Defendant Biopure admits it issued a press release dated December 11, 2003 and made a filing of the type listed and refers to that press release and that filing for the complete contents thereof. Further answering Biopure states that the July 30 letter regarding the BLA did not refer to itself as a complete

response letter and the FDA's conduct after the letter and after this Press Release confirmed it was not a complete response letter.

- 157. Defendants deny the allegations of Paragraph 157, except Defendant Biopure refers to historical price information regarding its stock price.
- 158. Defendants deny the allegations of Paragraph 158, except Defendant Biopure refers to historical price information regarding its stock price.
  - 159. Defendants deny the allegations in Paragraph 159.
- 160. Defendants deny the allegations of Paragraph 160, except Defendant Biopure admits that it issued a press release dated December 24, 2003 and a filing of the type listed on December 29, 2003 and refers to that press release and filing for the complete contents thereof.
- 161. Defendants deny the allegations of Paragraph 161, except Defendant Biopure admits that it issued a press release dated December 24, 2003 and refers to that press release for the complete contents thereof.
- 162. Defendants deny the allegations of Paragraph 162, except Defendant Biopure admits that it issued a press release dated December 24, 2003 and refers to that press release for the complete contents thereof.
  - 163. Defendants deny the allegations in Paragraph 163.
- 164. Defendants deny the allegations of Paragraph 164, except Defendant Biopure admits that it issued a press release dated December 24, 2003 and refers to that press release for the complete contents thereof.
- 165. Defendants deny the allegations in Paragraph 165, except that Defendant Biopure admits that it issued a press release dated December 24, 2003 and refers to that press release for the complete contents thereof.
- 166. Defendants deny the allegations in Paragraph 166, except Defendant Biopure refers to historical price information regarding its stock price.
  - 167. Defendants deny the allegations in Paragraph 167.

- 168. Defendants deny the allegations of Paragraph 168, except Defendant Biopure admits that it made a filing of the type listed on January 30, 2004 and refers to that filing for the complete contents thereof.
- 169. Defendants deny the allegations of Paragraph 169, except Defendant Biopure admits it issued a press release dated April 30, 2004 and refers to the that press release for the complete terms and contents thereof.
  - 170. Defendants deny the allegations in Paragraph 170.
  - 171. Defendants deny the allegations in Paragraph 171.
  - 172. Defendants deny the allegations in Paragraph 172.
  - 173. Defendants deny the allegations in Paragraph 173.
  - 174. Defendants deny the allegations in Paragraph 174.
  - 175. Defendants deny the allegations in Paragraph 175.
  - 176. Defendants deny the allegations in Paragraph 176.
  - 177. Defendants deny the allegations in Paragraph 177.
  - 178. Defendants deny the allegations of Paragraph 178.
  - 179. Defendants deny the allegations of Paragraph 179.
  - 180. Defendants deny the allegations of Paragraph 180.
- 181. Defendants are without knowledge or information sufficient to form a belief as to the truth of the statements of Paragraph 181.
- 182. Defendants are without knowledge or information sufficient to form a belief as to the truth of the statements of Paragraph 182.
- 183. Defendants are without knowledge or information sufficient to form a belief as to the truth of the statements of Paragraph 183.
- 184. Defendants are without knowledge or information sufficient to form a belief as to the truth of the statements of Paragraph 184.
  - 185. Defendants deny the allegations in Paragraph 185.

- 186. Defendants deny the allegations of Paragraph 186, except that Defendants Biopure and Rausch admit they were named as defendants in the class action referred to herein.
  - 187. Defendants deny the allegations in Paragraph 187.
  - 188. Defendants deny the allegations in Paragraph 188.
  - 189. Defendants deny the allegations in Paragraph 189.
- 190. Defendants deny the allegations in Paragraph 190, except Defendant Biopure admits that it made a filing of the type listed and refers to that filing for the complete contents thereof.
  - 191. Defendants deny the allegations in Paragraph 191.
  - 192. Defendants deny the allegations in Paragraph 192.
  - 193. Defendants deny the allegations in Paragraph 193.
  - 194. Defendants deny the allegations in Paragraph 194.
  - 195. Defendants deny the allegations in Paragraph 195.
  - 196. Defendants deny the allegations in Paragraph 196.
  - 197. Defendants deny the allegations in Paragraph 197.
  - 198. Defendants deny the allegations in Paragraph 198.
  - 199. Defendants deny the allegations in Paragraph 199.
  - 200. Defendants deny the allegations in Paragraph 200.
  - 201. Defendants deny the allegations in Paragraph 201.

# **CLASS ACTION ALLEGATIONS**

- 202. Defendants aver that the allegations in Paragraph 202 are Plaintiffs' legal conclusions to which no response is required. To the extent that Paragraph 202 may be deemed to contain any factual allegations, they are denied.
- 203. Defendants aver that the allegations in Paragraph 203 are Plaintiffs' legal conclusions to which no response is required. To the extent that Paragraph 203 may be deemed to contain any factual allegations, they are denied.

- 204. Defendants aver that the allegations in Paragraph 204 are Plaintiffs' legal conclusions to which no response is required. To the extent that Paragraph 204 may be deemed to contain any factual allegations, they are denied.
- 205. Defendants aver that the allegations in Paragraph 205 are Plaintiffs' legal conclusions to which no response is required. To the extent that Paragraph 205 may be deemed to contain any factual allegations, they are denied.
- 206. Defendants aver that the allegations in Paragraph 206 are Plaintiffs' legal conclusions to which no response is required. To the extent that Paragraph 206 may be deemed to contain any factual allegations, they are denied.
- 207. Defendants aver that the allegations in Paragraph 207 are Plaintiffs' legal conclusions to which no response is required. To the extent that Paragraph 207 may be deemed to contain any factual allegations, they are denied.
- 208 Defendants aver that the allegations in Paragraph 208 are Plaintiffs' legal conclusions to which no response is required. To the extent that Paragraph 208 may be deemed to contain any factual allegations, they are denied.
- 209. Defendants repeat and reallege their answers to Paragraphs 1 208 of the Complaint as if fully set forth herein.
  - 210. Defendants deny the allegations in Paragraph 210.
  - 211. Defendants deny the allegations in Paragraph 211.
  - 212. Defendants deny the allegations in Paragraph 212.
  - 213. Defendants deny the allegations in Paragraph 213.
  - 214. Defendants deny the allegations in Paragraph 214.
  - 215. Defendants deny the allegations in Paragraph 215.
  - 216. Defendants deny the allegations in Paragraph 216.
- 217. Defendants repeat and reallege their answers to Paragraphs 1 216 of the Complaint as if fully set forth herein.
  - 218. Defendants deny the allegations in Paragraph 218.

- 219. Defendants deny the allegations in Paragraph 219.
- 220. Defendants deny the allegations in Paragraph 220.
- 221. Defendants deny the allegations in Paragraph 221.
- 222. Defendants deny the allegations in Paragraph 222.
- 223. Defendants repeat and reallege their answers to Paragraphs 1 222 of the Complaint as if fully set forth herein.
  - 224. Defendants deny the allegations in Paragraph 224.
  - 225. Defendants deny the allegations in Paragraph 225.
  - 226. Defendants deny the allegations in Paragraph 226.

# **AFFIRMATIVE DEFENSES**

### FIRST AFFIRMATIVE DEFENSE

The Complaint, and each claim for relief, fails to state a claim upon which relief may be granted.

# SECOND AFFIRMATIVE DEFENSE

No misrepresentation, or false or misleading statement or omission was made by or on behalf of Defendants that directly or indirectly: (a) involved any material fact; (b) was relied upon by market participants, including investors; (c) caused or contributed to any loss or damage incurred by market participants, including investors; (d) was made in connection with the purchase or sale of any security by any market participant, including investors; (e) was made with any requisite level of scienter or intent to deceive; or (f) would operate as a fraud or deceit upon anyone.

### THIRD AFFIRMATIVE DEFENSE

Defendants did not employ any device, scheme or artifice to defraud, including any that directly or indirectly: (a) involved any material fact; (b) was relied upon by market participants, including investors; (c) caused or contributed to any loss or damage incurred by market

participants, including investors; (d) was made in connection with the purchase or sale of any security by any market participant, including investors; (e) was made with any requisite level of scienter or intent to deceive; or (f) would operate as a fraud or deceit upon anyone.

### FOURTH AFFIRMATIVE DEFENSE

Defendants did not engage in any act, practice, course of business or transaction that operated as a fraud or deceit, including any that directly or indirectly: (a) involved any material fact; (b) was relied upon by market participants, including investors; (c) caused or contributed to any loss or damage incurred by market participants, including investors; (d) was made in connection with the purchase or sale of any security by any market participant, including investors; or (e) was made with any requisite level of scienter or intent to deceive.

#### FIFTH AFFIRMATIVE DEFENSE

Defendants did not obtain any money or property by any means that directly or indirectly:

(a) involved in any way any untrue statement of material fact or omission to state material facts necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading; (b) was relied upon by market participants, including investors; (c) caused or contributed to any loss or damage incurred by market participants, including investors; (d) was made in connection with the purchase or sale of any security by any market participant, including investors; (e) was made with any requisite level of scienter or intent to deceive; or (f) would operate as a fraud or deceit upon anyone.

### SIXTH AFFIRMATIVE DEFENSE

The statements alleged in the Complaint to have been made (or omitted), if any were in fact made (or omitted), had a basis in fact or a reasonable basis.

### SEVENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred because Defendants at all times acted in good faith, exercised reasonable due diligence, and because Defendants had after reasonable investigation, reasonable grounds to believe and did believe, at the time such statements were made (if any), that such statements were true and/or not misleading.

### EIGHTH AFFIRMATIVE DEFENSE

The Complaint, and each claim for relief, fails to plead fraud with sufficient particularity.

# NINTH AFFIRMATIVE DEFENSE

Defendants complied faithfully with all duties of disclosure to which the Defendants were subject, if any, and breached no duty of disclosure applicable to them.

### TENTH AFFIRMATIVE DEFENSE

The business judgment rule protects Defendants' alleged actions or failures to act and, thus, bars Plaintiffs' claims.

# ELEVENTH AFFIRMATIVE DEFENSE

If anyone suffered loss or damages, which Defendants deny, that loss or damages resulted from causes other than any alleged act or omission by Defendants.

# TWELFTH AFFIRMATIVE DEFENSE

The fraud-on-the-market theory is not a basis of liability with respect to any of the claims in this action.

### THIRTEENTH AFFIRMATIVE DEFENSE

The statements alleged in the Complaint to have been made, if any were in fact made, were forward-looking statements protected by applicable safe harbor provisions.

# FOURTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, because Defendants' public statements, registration statement/prospectus, prospectus supplements, and annual and quarterly filings with the SEC, sufficiently bespoke caution.

### FIFTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, by applicable statutes of limitation and/or the doctrines of laches, and/or estoppel, and/or unclean hands and/or waiver.

# SIXTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, because there was no culpable participation.

# SEVENTEENTH AFFIRMATIVE DEFENSE

The Defendants did not know, and in the exercise of reasonable care could not have known, of the alleged untruths or omissions set forth in the Complaint.

# EIGHTEENTH AFFIRMATIVE DEFENSE

The statements alleged by Plaintiffs to have been misrepresentations constitute statements of opinion, of conditions to exist in the future, and of matters promissory in nature, and other types of non-actionable statements.

# NINETEENTH AFFIRMATIVE DEFENSE

The Defendants had no duty to disclose any allegedly omitted information set forth in the Complaint.

# TWENTIETH AFFIRMATIVE DEFENSE

This action is not maintainable as a class action under Rule 23 of the Federal Rules of Civil Procedure because, alternatively,

(a) Plaintiffs will not fairly and adequately protect the interests of the class on behalf of which they purport to bring this action.

- (b) Plaintiffs' claims are not typical of the claims of the purported class.
- (c) Questions of law or fact common to the purported class do not predominate over questions affecting only individual members of the purported class.
- (d) Part or all of the purported class is not numerous.
- (e) The other requirements of Fed. R. Civ. P. 23 have not been met.

### TWENTY-FIRST AFFIRMATIVE DEFENSE

If Plaintiffs have suffered any injury, which is denied, such injury was caused by the Plaintiffs' own acts or omissions, or by the acts or omissions of third parties over which Defendants have no control.

# TWENTY-SECOND AFFIRMATIVE DEFENSE

Plaintiffs have failed to mitigate their damages.

# TWENTY-THIRD AFFIRMATIVE DEFENSE

Defendants hereby give notice that it intends to rely upon such other and further defenses as may become available or apparent during pretrial proceedings in this action and hereby reserves its rights to amend its answer and assert all such defenses.

# PRAYERS FOR RELIEF

WHEREFORE, Defendants respectfully request that this Court:

- 1. Enter judgment in its favor dismissing the Complaint and all of its claims with prejudice;
- 2. Award Defendants their costs and attorneys' fees in defending this action; and
- 3. Grant Defendants such other and further relief as may be just and appropriate.

# **DEMAND FOR JURY TRIAL**

Biopure hereby demands a jury on all issues so triable.

Respectfully submitted,

BIOPURE CORPORATION, THOMAS A. MOORE, HOWARD P. RICHMAN. RONALD F. RICHARDS, CARL W. RAUSCH, CHARLES A. SANDERS AND J. RICHARD CROUT,

By its attorneys,

### /s/ Robert A. Buhlman

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Attorney for Defendant Ronald F. Richards

/s/ Christopher F. Robertson Christopher F. Robertson, BBO # 642094 SEYFARTH SHAW LLP Two Seaport Lane, Suite 300 Boston, MA 02210 (617) 946-4800

Dated: April 28, 2006

# **CERTIFICATE OF SERVICE**

I hereby certify that a true copy of the above pleading was electronically served upon the attorneys of record for all parties on April 28, 2006.

/s/ Robert A. Buhlman Robert A. Buhlman